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10/506,423

12/01/2004

Sylvana P Muller

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JACOBSON HOLMAN PLLC
400 SEVENTH STREET N.W.
SUITE 600
WASHINGTON, DC 20004

EXAMINER

CHONG, YONG SOO

ART UNIT

PAPER NUMBER

1617

MAIL DATE

DELIVERY MODE

05/05/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/506,423 | Applicant(s) MULLER ET AL. | |
| | Examiner YONG S. CHONG | Art Unit 1617 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-26 is/are pending in the application.
- 4a) Of the above claim(s) 21-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-20 and 24-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

This Office Action is in response to applicant's arguments filed on 2/23/09.

Claim(s) 1-10 have been cancelled. Claim(s) 11-26 have been added. Claim(s) 11-26 are pending.

Newly submitted claims 21-23 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the pathological conditions recited in claims 21-23 are patentably distinct from the conditions originally elected for examination.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 21-23 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Therefore, claims 11-20, 24-26 are examined herein.

Applicant's amendments to the claims have rendered the 112 and 101 rejections of the last Office Action moot, therefore hereby withdrawn.

Applicant's arguments regarding the 102 rejections of the last Office Action have been fully considered but found not persuasive. They are maintained for reasons of record and modified below as a result of the new claim amendments.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim(s) 11-14, 16-20, 24-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Enzmann et al. (US Patent 6,228,891 B1, of record) as evidenced by Applicant's admission of the prior art.

Enzmann et al. teach the topical or oral administration of 2,3-dimethyl-5-methyl-6-decaprenyl-1,4-benzoquinone (also called ubidacarenone) for the treatment of diseases of the cardiovascular system, the lung, the muscles, the stomach and bowels, the skin, incontinence, asthma (bronchoconstriction of the lung), acne, psoriasis, and eczema (col. 1, lines 1-33).

Applicant's admission of the prior art includes the statement that histamines, PAF, and leukotrienes are central mediators of inflammatory reactions (pg. 1 and 3). Therefore, the limitations drawn to "influencing the activity of histamines and other mediators" such as "PAF and leukotrienes" are inherent since the same diseases that are recited to be related to these mediators in the pending claims are also taught by Enzmann et al.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim(s) 11-15, 18-20, 26 are rejected under 35 U.S.C. 102(e) as being anticipated by Nyce (US Patent Application 2002/0032160 A1) as evidenced by Applicant's admission of the prior art.

Nyce teach the use of composition comprising ubiquinones for the treatment of bronchoconstriction, respiratory tract inflammation, allergies, and asthma (abstract). These compositions may be in the form of particles having a size of 10 to 500 nm (paragraph 0040). Oral and parental administration are taught (claims).

Applicant's admission of the prior art includes the statement that histamines, PAF, and leukotrienes are central mediators of inflammatory reactions (pg. 1 and 3). Therefore, the limitations drawn to "influencing the activity of histamines and other mediators" such as "PAF and leukotrienes" are inherent since the same diseases that are recited to be related to these mediators in the pending claims are also taught by Nyce.

Response to Arguments

Applicant argues against both Enzmann and Nyce because they do not specifically teach that Q10 is used as an anti-histamine or that Q10 has anti-histamine properties.

This is not persuasive because this property is inherent to the compound. Applicant is encouraged to show factual evidence that Q10 does not have anti-histamine properties. Furthermore, this limitation is not in the claims.

“Products of identical chemical composition can not have mutual exclusive properties.” Any properties exhibited by or benefits from are not given any patentable weight over the prior art provided the composition is inherent. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the disclosed properties are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. The burden is shifted to the applicant to show that the prior art product does not inherently possess the same properties as the instantly claimed product.

Applicant argues that Enzmann does not teach bronchoconstriction of the lung. This is not persuasive because asthma is taught by the reference. It is obvious to one of ordinary skill in the art that asthma is characterized by bronchoconstriction of the lung.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Art Unit: 1617

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/YONG S. CHONG/
Primary Examiner, Art Unit 1617

YSC